



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 112430.134US2)

In re Application of: Lee et al.

Serial No: 09/284,297

Filing Date: July 5, 2000

Examiner: N. Levy

Art Unit: 1616

RECEIVED

AUG 16 2002

OFFICE OF PETITIONS

Title: METHOD OF PREPARING A POORLY CRYSTALLINE CALCIUM PHOSPHATE AND
METHOD OF ITS USE

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on the date indicated below

August 1, 2002
Date

Rebecca S. Tinio
Printed Name of Person Mailing Correspondence

[Signature]
Printed Name of Person Mailing Correspondence

Commissioner for Patents
Washington, D.C. 20231

**PETITION PURSUANT TO 37 C.F.R. §1.137(b) TO REVIVE AN UNINTENTIONALLY
ABANDONED PATENT APPLICATION**

Dear Sir:

A Notice of Abandonment (copy attached) was mailed on March 28, 2002 in the above-referenced application. The indicated reason for abandonment is failure to timely respond to the May 23, 2001 within the statutory period of time. Applicants submit that the application went abandoned unintentionally. The application file became misplaced when it was transferred to the current agent of record address from the previous agent of record address and was not timely entered into the docket system that monitors application deadlines. Upon recovery of the file, the undersigned began preparation of a response that is being filed today with this Petition to Revive.

Applicants hereby petition to revive this application and requests that the abandonment of the application be withdrawn and that the enclosed Reply to Examiner's Action be considered

Please charge our Deposit Account No. 08-0219 for the \$640.00 petition fee and any other fees which might be due in connection with this matter.

08/09/2002 AMONDAF1 00000019 080219 09284297

01 FC:241 640.00 CH

It is respectfully requested that all communications for this application be mailed to the attention of the attorney of record at the following address:

MaryRose Scozzafava, Ph.D.
Hale and Dorr LLP
60 State Street
Boston, MA 02109

If there are any questions in connection with this submission, please contact the undersigned.

Respectfully submitted,
HALE AND DORR LLP

Date: August 1, 2002
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000
(617) 526-5000 (Facsimile)

Mary Rose Scozzafava
MaryRose Scozzafava, Ph.D., Reg. No. 36,268
Attorney/Agent for Applicants

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

OFFICE TRANSMITTAL
AUG 06 2002
PATENT & TRADEMARK OFFICE
Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$) 640.00

Complete if Known

Application Number	09/284,297
Filing Date	07/05/2000
First Named Inventor	Dosuk D. Lee
Examiner Name	N. Levy
Group Art Unit	1616
Attorney Docket No.	112430.134US2

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: 08-0219

Deposit Account Name: Hale and Dorr LLP

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☒ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ Payment Enclosed:

☐ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
101 740	201 370	Utility filing fee	
106 330	206 165	Design filing fee	
107 510	207 255	Plant filing fee	
108 740	208 370	Reissue filing fee	
114 160	214 80	Provisional filing fee	
SUBTOTAL (1)			(\$) 0.00

2. EXTRA CLAIM FEES

Total Claims: - 20** = X =

Independent Claims: - 3** = X =

Multiple Dependent Claims: =

Large Entity Fee Code (\$) **Small Entity Fee Code (\$)** **Fee Description**

103 18	203 9	Claims in excess of 20	
102 84	202 42	Independent claims in excess of 3	
104 280	204 140	Multiple dependent claim, if not paid	
109 84	209 42	** Reissue independent claims over original patent	
110 18	210 9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)			(\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued) **RECEIVED**
AUG 16 2002
OFFICE OF PATENTS

3. ADDITIONAL FEES

Fee Code	Large Entity (\$)	Small Entity (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath		
127 50	227 25	Surcharge - late provisional filing fee or cover sheet		
139 130	139 130	Non-English specification		
147 2,520	147 2,520	For filing a request for <i>ex parte</i> reexamination		
112 920*	112 920*	Requesting publication of SIR prior to Examiner action		
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action		
115 110	215 55	Extension for reply within first month		
116 400	216 200	Extension for reply within second month		
117 920	217 460	Extension for reply within third month		
118 1,440	218 720	Extension for reply within fourth month		
128 1,960	228 980	Extension for reply within fifth month		
119 320	219 160	Notice of Appeal		
120 320	220 160	Filing a brief in support of an appeal		
121 280	221 140	Request for oral hearing		
138 1,510	138 1,510	Petition to institute a public use proceeding		
140 110	240 55	Petition to revive - unavoidable		
141 1,280	241 640	Petition to revive - unintentional	640.00	
142 1,280	242 640	Utility issue fee (or reissue)		
143 460	243 230	Design issue fee		
144 620	244 310	Plant issue fee		
122 130	122 130	Petitions to the Commissioner		
123 50	123 50	Processing fee under 37 CFR 1.17(q)		
126 180	126 180	Submission of Information Disclosure Stmt		
581 40	581 40	Recording each patent assignment per property (times number of properties)		
146 740	246 370	Filing a submission after final rejection (37 CFR § 1.129(a))		
149 740	249 370	For each additional invention to be examined (37 CFR § 1.129(b))		
179 740	279 370	Request for Continued Examination (RCE)		
169 900	169 900	Request for expedited examination of a design application		
Other fee (specify) _____				
SUBTOTAL (3)			(\$) 640.00	

*Reduced by Basic Filing Fee Paid

SUBMITTED BY

Name (Print/Type)	Mary Rose Scozzafava, Ph.D.	Registration No. (Attorney/Agent)	36,268	Telephone	(617)526-6015
Signature	Mary Rose Scozzafava			Date	08/01/2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

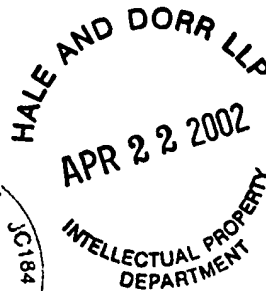


UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,297	07/05/2000	Dosuk D. Lee	04712/02000G	2121

7590 03/28/2002
Mary Rose Scozzafava
Clark & Elbing
176 Federal Street
Boston, MA 02110



EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/28/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

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OFFICE OF PETITIONS

HALE & DORR DOCKETING

112432-134 US2

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by Ag on 4.24.02



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

COPY OF PAPERS
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EXAMINER	
ART UNIT	PAPER NUMBER
	18

DATE MAILED:

NOTICE OF ABANDONMENT

RECEIVED

AUG 16 2002

OFFICE OF PETITIONS

This application is abandoned in view of:

- ☒ Applicant's failure to respond to the Office letter, mailed 5/23/01.
- ☐ Applicant's letter of express abandonment which is in compliance with 37 C.F.R. 1.138.
- ☐ Applicant's failure to timely file the response received _____ within the period set in the Office letter.
- ☐ Applicant's failure to pay the required issue fee within the statutory period of 3 months from the mailing date of _____ of the Notice of Allowance.
 - ☐ The issue fee was received on _____.
 - ☐ The issue fee has not been received in Allowed Files Branch as of _____.

In accordance with 35 U.S.C. 151, and under the provisions of 37 C.F.R. 1.316(b), applicant(s) may petition the Commissioner to accept the delayed payment of the issue fee if the delay in payment was unavoidable. The petition must be accompanied by the issue fee, unless it has been previously submitted, in the amount specified by 37 C.F.R. 1.17(l), and a verified showing as to the causes of the delay.

If applicant(s) never received the Notice of Allowance, a petition for a new Notice of Allowance and withdrawal of the holding of abandonment may be appropriate in view of *Delgar Inc. v. Schuyler*, 172 U.S.P.Q. 513.

- ☐ Applicant's failure to timely correct the drawings and/or submit new or substitute formal drawings by _____ as required in the last Office action.
 - ☐ The corrected and/or substitute drawings were received on _____.
- ☐ The reason(s) below.

Called attorney - case was transferred - no response was filed 3/25/02

NEIL S. LEVY
PRIMARY EXAMINER



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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/284,297 07/05/00 LEE

EXAMINER

HM22/0523

ART. UNIT	PAPER NUMBER
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MARY ROSE SCOZZAFAVA
CLARK & ELBING
176 FEDERAL STREET
BOSTON MA 02110

DOCKETED FOR
ATTORNEY ATTENTION DATE MAILED: 05/23/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

RECEIVED 05/23/01
Clark & Elbing LLP
AUG 16 2002

OFFICE ACTION SUMMARY

OFFICE OF PETITIONS: 2 9 2001

315701

☒ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 40, 42, 43, 103, 111-148 is/are pending in the application.
Of the above, claim(s) 121, 135, 146 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 40, 42, 43, 103, 111-120, 122-134, 136-145, 147 & 148 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 40, 42, 43, 103, 111-148 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

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Applicant's election without traverse of bone protein and demineralized bone in Paper No. 15 is acknowledged.

Claims 121, 135 and 146 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 15.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 or 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 43, 103, 111-120, 122-134, 136-145, 147 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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“Compact”, “Promoter”, “Predetermined”, “Strongly”, “Poorly”, “intimate”, “supplemental”, “selected”, “characteristic” are all indefinite, ambiguous or relative terms, and fail to impart specificity to permit identification of the meets and bounds of the subject matter of the invention as it is claimed. So is “suitable”, “associated with”, “derivativized”. There is no antecedent for “conversion” of claim 111.

Claims 40, 42, 43, 103, 111-120, 122-134, 136-143, 145, 147, 148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of ordinary skill in the bioceramic arts would not know how and what to prepare and under what condition, in order to arrive at the claimed, poorly identified, compositions, composites and method. It is not clear how pressing is done in vivo (claim 113).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Art Unit: 1616

Claims 40, 42, 43, 103, 111-114, 116-118, 120, 122, 124, 126-131, 133, 134, 136, 138-145, 147, 148 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantz et al 5782971.

See claim 1; the compositions of the instant invention; ~~of~~ of instant claims 42, 43. Instant 111, 114, 116-118, 120, 122, 124, 126-131, 133, 134, 136, 138-145, 147 and 148 are encompassed, as the materials of the instant claims are present, prepared in the instant manner, thus inherently providing the instant characteristics--These are shown at Constantz claims 1-4, 7-20, and, for (claim 40) pressing and mixing, at Col. 8, B. for incubation at 37° (claim 112) at col. 8; III, A. In vivo application is presented at Col. 9, line 30-43, summary ~~and~~ col. 6, bottom. Bioactives are at col. 5 and 6. The x-ray diffraction is a function of the conversion to hydroxyapatite--inherently it would be seen--see claim 16 - 18. The same ingredients and procedures are performed and provided as is INSTANTLY claimed, thus, the same aspects, characteristics and functions would inherently be present.

Claims 40, 42, 43, 103, 111-114, 116-120, 122-134, 136-145, 147, 148 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Constantz 4880610.

Constantz teaches one can utilize either endothermic, exothermic or no change in mix temperature (col. 3, top), as desired. Also disclosed are amorphous, or crystalline polyphosphoric compounds, prepared dry or as liquids. Ca/P ~~of~~ hydroxy apatite is taught, as the ratio: to be achieved (paragraph 2). PH is shown as 5-9 (paragraph 4). Ground bone, collagen,

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morphogenetic protein maybe incorporated (col. 4). Mixing, shaping and packing is taught (col. 5) DCPD is disclosed at Example 1, as are x-ray diffraction analyses similar to the instant. The desired amount of hydroxy apatite will be determined by the artisan, and thus determine the X-ray pattern (col. 6, lines 10-50). Example 2 shows rat implantation, thus, the same characteristics as are instantly claimed would be evident as expected results of the same process as of the instant invention.

Claims 40, 42, 43, 103, 111-120, 122-134, 136-145, 147, 148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al 5782971 in view of Constantz 4880610 and Fukase et al '90.

Constantz, '578 (above) discloses paste compositions and bioceramic composites and preparation as of the instant invention used in the instant methods, but does not encompass all of the forms. The mechanisms of action are not fully presented. Constantz, however, teaches one can utilize either endothermic, exothermic or no change in mix temperature (col. 3, top), as desired. Also disclosed are amorphous or crystalline polyphosphoric compounds, prepared dry or as liquids. Ca/P of hydroxy apatite is taught, as the ratio to be achieved (paragraph 2). PH is shown as 5-9 (paragraph 4). Ground bone, collagen, morphogenetic protein maybe incorporated (col. 4). Mixing shaping and packing is taught (col. 5) DCPD is disclosed at Example 1, as are X-ray diffraction analyses similar to the instant. The desired amount of hydroxy apatite will be determined by the artisan, and thus determine the X-ray pattern (col. 6, line 10-50). Example 2 shows rat implantation, thus, the same characteristics would be expected as are instantly claimed.

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Lyophilization is shown by Fukase (summary) as well with in the skill of one in the bioceramic arts to accomplish.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective, stable bone treatment composition to utilize Constantz with improvements as taught by Constantz et al, of artisans choice, while Fukase further teaches one having ordinary skill in the art would be motivated to perform this modification in order to achieve greater stability, ease of handling, and action, and strength of the bone compositions.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the use of specific Ca/P sources, bioactives, carriers promotes and other adjuvants common to the art as means of bone repair and the use ingredients for the functionality for which they are known to be used is not a basis for patentability.

Claims 40, 42, 43, 111-120, 126-134, 138-145, 148 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al 6201039 B1.

See summary, Examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7:00 am to 5:30 pm.

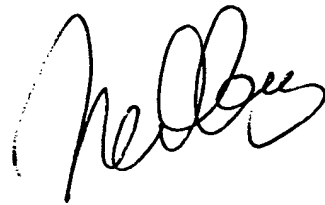
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Art Unit: 1616

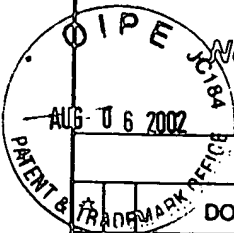
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

May 18, 2001

A handwritten signature in black ink, appearing to read "Neil S. Levy". The signature is fluid and cursive, with the first name "Neil" and last name "Levy" clearly distinguishable.

**NEIL S. LEVY
PRIMARY EXAMINER**



Application No.

Applicant(s)

Examiner

Group Art Unit

Page 16

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	6201039B1	3/2001	Brown et al	523	115
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

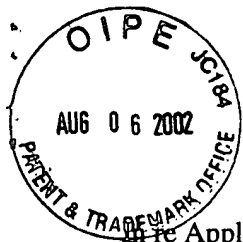
FOREIGN PATENT DOCUMENTS

*	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

*	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

* A copy of this reference is not being furnished with this Office action.
(See Manual of Patent Examining Procedure, Section 707.05(a).)



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 112430.134US2)

Re Application of: Lee et al.

) Examiner: N. Levy

Serial No: 09/284,297

) Art Unit: 1616

Filing Date: July 5, 2000

Title: METHOD OF PREPARING A POORLY CRYSTALLINE CALCIUM PHOSPHATE AND
METHOD OF ITS USE

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on the date indicated below.

August 1, 2002

Date

Rebecca S. Tinio

Printed Name of Person Mailing Correspondence

Rebecca S. Tinio

Printed Name of Person Mailing Correspondence

RECEIVED

AUG 16 2002

Commissioner for Patents
Washington, D.C. 20231

OFFICE OF PETITIONS

TRANSMITTAL

Dear Sir:

Enclosed herewith for filing in the above-referenced patent are the following documents:

1. Petition Under 37 C.F.R. 1.137(b) to Revive an Unintentionally Abandoned Patent Application;
2. Reply to Examiner's Action;
3. Petition Fee of \$640.00;
4. Certificate of First Class Mailing; and
5. Return Postcard.

No additional fees are believed to be due in connection with this matter. However, please charge any additional fees which might be due to Deposit Account No. 08-0219.

If there are any questions in connection with this submission, please contact the undersigned.

Respectfully submitted,
HALE AND DORR LLP

Date: August 1, 2002
HALE AND DORR LLP
60 State Street
Boston, MA 02109
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(617) 526-5000 (Facsimile)

Mary Rose Scozzafava
MaryRose Scozzafava, Ph.D., Reg. No. 36,268
Attorney/Agent for Applicants